



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Food and Drug Administration  
Cincinnati District Office  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2772

**WARNING LETTER**

Cin WL-7127-01  
April 3, 2001

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Terrance L. Johnson, M.D.  
Partner  
T. L. Johnson, M.D. & R. C. Adams, M.D.  
1178 Professional Dr.  
Box 707  
Van Wert, OH 45891

Facility I.D.#: 183194

Dear Dr. Johnson:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on March 5, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **repeat** Level 2 finding at your facility:

**Medical Records and Mammography Reports – *Contents and Terminology***  
**21 CFR 900.12 (c)(1)(iv)(A)-(E) & (v)**

Two of ten random interpreting physician mammography reports did not contain the required overall final assessment of findings.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and **indicates failure by your facility to implement permanent correction of the problem found during your previous inspection.**

Because the condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of

your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

The other three items listed in your March 5, 2001 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address the Level 3 items in your written response.

It is necessary for you to act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violation noted in this letter; and
- Each step your facility is taking **to prevent the recurrence** of similar violation.

Please submit sample records that demonstrate proper record keeping procedures, if the finding relates to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen  
MQSA Compliance Officer  
Food & Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
FAX: 513-679-2772


Also, please send a copy to the State radiation control office:

Ms. Cindy Grant  
Ohio Department of Health  
Radiologic Technology Section  
1 Government Center  
Suite 1320  
Toledo, OH 43604

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to finding of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

  
for Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
OH/C Grant

Priscilla F. Butler, M.S.  
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American College of Radiology  
1891 Preston White Dr.  
Reston, VA 20191